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UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of KORANGY RADIOLOGY ASSOCIATES, P.A., trading as BALTIMORE IMAGING CENTERS, a corporation, and AMILE A. KORANGY, M.D., an individual.	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTIES FDA Docket No. 2003H-0432

PARTIAL SUMMARY DECISION

Complainant, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), brought an action on September 22, 2003 seeking civil money penalties against Respondents Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers (BIC), and Amile A. Korangy, M.D., alleging that Respondents violated the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. Complaint submitted a Motion for Partial Summary Judgment pursuant to 21 C.F.R. § 17.17 on April 2, 2004, seeking a summary decision on the issue of Respondents' liability for alleged violations of the MQSA.

PROCEDURAL HISTORY

On September 22, 2003, CDRH filed a complaint for civil money penalties against Respondents, alleging that between May 7, 2002 and July 25, 2002, BIC was not certified to perform mammography procedures but continued to do so, violating the MQSA. On October 17,

2003, an Answer of Respondents to the CDRH complaint was filed and a hearing was requested. On November 13, 2003, a final scheduling Order was issued. On December 2, 2003, Respondents filed a Supplement to Answer.

On April 2, 2004, Complainant's Motion for Partial Summary Judgment was filed. On April 30, 2004. Respondents filed an Opposition of Respondents to Complainant's Motion for Partial Summary Judgment, and a Memorandum in Support of Opposition of Respondents to Complainant's Motion for Partial Summary Judgment. On May 21, 2004, Complainant submitted a Reply to Respondent's Opposition to Complainant's Motion for Partial Summary Judgment.

DISCUSSION OF FACTS

The MQSA provides that no facility may conduct an examination or procedure involving mammography unless it obtains a certificate that has been issued or renewed under the MQSA. 42 U.S.C § 263b(b)(1). Complainant alleges that Respondents violated this provision of the MQSA and are thus liable for civil penalty sanctions pursuant to 42 U.S.C. § 263b(h).

On May 6, 1999, FDA issued a mammography certificate to Respondents enabling them to lawfully perform mammography examinations and procedures at the BIC facility where Dr. Korangy was the lead interpreting physician, operator, owner, and employee of BIC at the time of the alleged violations. Exhibit G-D ¶ 11; Exhibit G-A; Exhibit G-B; Exhibit G-C. A certificate is generally effective for a period of three years after the date that it is issued or renewed. 42 U.S.C. § 263b(c)(1); Exhibit G-D ¶ 9. Thus, Respondents' certificate was set to expire on May 6, 2002. Exhibit G-D ¶ 11; Exhibit G-4. Complainant alleges that Dr. Korangy was responsible for maintaining BIC's certification under the MQSA. Exhibit G-E ¶ 8; Exhibit G-D ¶ 17; Exhibit G-6.

On April 1, 2002 FDA sent a letter to Respondents informing them that BIC's certificate was set to expire on May 6, 2002 unless BIC was re-accredited by an FDA approved accreditation body. Exhibit G-D ¶ 11; Exhibit G-1. The letter also informed Respondents that BIC could no longer perform mammography services once its certificate expired. Id. The April 1, 2002 letter stated to Respondents' that their "Mammography Facility Certificate will expire on 05/06/2002. Under the Mammography Quality Standards Act (MQSA) of 1992, once your certificate expires, you are **no longer certified and cannot continue to offer mammography services.**" Exhibit G-1.

Respondents were mailed a letter dated April 29, 2002 from the American College of Radiology (ACR), an FDA-approved accreditation body. ACR found that the mammograms produced by BIC failed to comply with ACR's standards for clinical image quality and strongly recommended that BIC immediately cease performing mammography examinations. Exhibit G-D ¶ 12; Exhibit G-2. The April 29, 2002 letter states, "**ACR strongly recommends that you cease conducting mammography with this unit upon receipt of this letter.** As an FDA-approved accrediting body, the ACR is required to notify the FDA of this failure and the FDA will officially notify you to discontinue mammography with this unit." Exhibit G-2.

According to Elizabeth A. Laudig, a Compliance Officer in the FDA Baltimore District Office, Dr. Korangy discussed the April 29, 2002 letter from ACR with Barry J. Henderson, BIC's Vice President. See Exhibit G-E ¶ 11; Exhibit G-11. Complainant alleges that Dr. Korangy and Mr. Henderson decided that the mammograms produced by BIC were acceptable, and that BIC would continue to perform mammography examinations. Id.

On May 1, 2002, FDA sent a letter to Respondents instructing them to cease performing uncertified mammography procedures. The letter instructed Respondents, "**[u]pon receipt of**

this letter, you must cease performing mammography and you should no longer display your certificate, regardless of the date of expiration. The...[MQSA] authorizes FDA to take regulatory action, including suspension or revocation of certification and civil money penalties, against facilities that practice mammography in violation of the law." Exhibit G-3; Exhibit G-D ¶ 13. A technologist at BIC signed for the receipt of FDA's May 1, 2002 letter to Respondents. Exhibit G-E ¶ 12; Exhibit G-D ¶ 13; Exhibit G-3.

On May 6, 2002 Respondents' certificate expired. Exhibit G-4; Exhibit G-D ¶ 14. However, Respondents continued to perform mammography examinations at their facility. FDA investigators conducted an inspection of BIC during August and September, 2002 to determine whether Respondents had performed mammography without a valid certificate. Exhibit G-E ¶ 5. During inspections, investigators collected documents for mammography examinations that Respondents conducted between May 7, 2002 and July 25, 2002. Exhibit G-E ¶ 10; Exhibit G-D ¶ 21; Exhibit G-10. These reports show that Respondents conducted 192 mammography examinations between and including May 7, 2002, and July 25, 2002. Exhibit G-D ¶ 21. Respondents do not deny that they conducted 192 mammography examinations during this period.

Respondents claim that prior to July, 2002 they received no notice from FDA or ACR indicating that they should cease and desist performing mammography examinations. Memorandum in Support of Opposition of Respondents to Complaint's Motion for Partial Summary Judgment ¶ A. 6. In their Answer of Respondents dated October 17, 2003, Respondents denied many of Complainant's allegations, including that their certificate expired on May 6, 2002—without elaboration, asserting that they "did not receive a written

communication from FDA indicating that they would be in legal violation to continue to perform mammography during the time period in question."

In Respondents' Opposition to Complainant's Motion for Partial Summary Judgment submitted April 30, 2004, Respondents alleged that they received neither the letter of April 1, 2002 nor the May 1, 2002 letter. Exhibit R-1 (Korangy Decl.). In the Memorandum in Support of Opposition of Respondents to Complaint's Motion for Partial Summary Judgment, Respondents allege that there is no record of anyone representing the Respondents having received the May 1 letter. Dr. Korangy alleges that the receipt for the letter dated May 1, 2002 contains a signature that he does not recognize. Exhibit R-1. Dr. Korangy alleges that he did receive the ACR letter of April 29, 2002, but understood it to contain a recommendation that Respondents not continue to use the old machine, and not that Respondents should permanently discontinue providing mammography. Id.

Respondents allege that they believed in May, June and July of 2002 that they were following ACR and FDA procedures in replacing their existing mammography equipment with new equipment, and were unaware that FDA intended that they cease performing mammography services. Respondents' Opposition to Complainant's Motion for Partial Summary Judgment. Dr. Korangy declares that the old machine was retired in May or June of 2002 and that he believed that between May and July of 2002, Respondents had responded appropriately to ACR's concerns by promptly ordering a new mammography machine, and installing it as soon as possible. Exhibit R-1. Dr. Korangy proclaims that Respondents ordered the new equipment in March 2002. Id. Dr. Korangy claims that contacts with ACR in May had assured Respondents that the process that they were following comported with FDA requirements; Dr. Korangy alleges that in neither of two conversations with ACR in May 2002, when Respondents allegedly

reported the purchase of a new mammography machine and sought to obtain clarification of the process to maintain certification, were Respondents made aware that BIC was to have ceased performing mammography procedures on May 6, 2002. Exhibit R-1. Respondents claim that Dr. Korangy and Mr. Henderson did not decide, as alleged by FDA, that the quality of the pre-existing mammography equipment was acceptable. Exhibit R-1; Exhibit R-2 (Henderson Decl.).

On July 18, 2002, ACR sent a letter to Complainant describing ACR's concern that, despite its lack of certification, BIC was continuing to perform mammography. Exhibit G-D ¶ 15; Exhibit G-5. As a result of this letter, Complainant contacted FDA's Baltimore District Office and requested that it conduct an inspection of BIC. Exhibit G-D ¶ 16.

According to records, Respondents installed a new mammography unit in the BIC facility on or around June 28, 2002. Exhibit G-E ¶ 13; Exhibit G-12. On July 22, 2002, Dr. Korangy submitted a reinstatement application to ACR. Exhibit G-D ¶ 17; Exhibit G-6; Exhibit G-7. In the application, Dr. Korangy indicated that BIC had corrected its clinical image deficiencies by, among other things, purchasing a new mammography unit. Id. On July 24, 2002, ACR notified FDA that BIC's application for accreditation reinstatement was sufficiently complete for review, and that BIC was eligible for provisional reinstatement. Exhibit G-D ¶ 18. On July 26, 2002, FDA issued an interim notice that served as BIC's certification to conduct mammography services until it received a permanent certificate. Exhibit G-D ¶ 19; Exhibit G-8; Exhibit G-9.

Respondents deny having received various letters of notice from ACR and FDA. The Complainant's allegations to the contrary have not (to date) been subjected to the reliability considerations required by due process. Therefore, the question of Respondents having received written notice of any violations cannot be definitively answered prior to Complainant's submissions being received into evidence. In view of their denial, due process requires that

Respondents have the opportunity to test Complainant's evidentiary submissions by all means available, including the cross-examination of witnesses.

Nevertheless, even if Respondents did not view any of the letters, it is clear that they should have been on notice of their continuing violations of the MQSA. Although Respondents deny that their certificate expired on May 6, 2002, Exhibit G-4 clearly indicates May 6, 2002 as an expiration date, and there is no allegation that Exhibit G-4 is not a valid copy of the actual certificate. Therefore, Respondents knew or should have known that the performance of mammography after the expiration date (without any renewal or re-certification) constitute continuing violations of the MQSA. As a matter of law, this conduct constitutes violation of 42 U.S.C. § 263b(b)(1) for which Respondents may be held liable, regardless of whether Respondents actually received the letters sent to them by FDA.

DISCUSSION OF LAW

Pursuant to 21 C.F.R. § 17.17(a), "[a]t any time after the filing of a complaint, a party may move...for a summary decision on any issue in the hearing." A motion for summary decision shall be granted "if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b). Where "a motion for summary decision is made and supported as provided in [21 C.F.R. § 17.17], a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing." 21 C.F.R. § 17.17(c).

Under the MQSA, no mammography facility may conduct a mammography examination or procedure unless it possesses an effective certificate that has been issued or renewed under the

MQSA. 42 U.S.C. § 263b(b)(1). In order to obtain or renew a certificate, the MQSA, and its implementing regulations, require a facility to apply to, and be accredited by, an FDA-approved accreditation body. 42 U.S.C. § 263b(d)(1); 21 C.F.R. §§ 900.11(a) and (b). Once FDA receives notification of the accreditation body's decision to accredit a facility, FDA may issue a certificate to the facility or renew the facility's existing certificate. 21 C.F.R. § 900.11(b)(ii).

Where a previously certified facility has allowed its certificate to expire or has been refused a renewal, the facility may apply to an accreditation body to have its certificate reinstated. 21 C.F.R. § 900.11(c). FDA may issue a provisional certificate to the facility once the accreditation body notifies FDA that the facility has corrected the deficiencies that led to the lapse of its certificate. 21 C.F.R. § 900.11(c)(2). A facility may lawfully perform mammography services once it receives a provisional certificate. 21 C.F.R. § 900.11(c)(3).

Under 42 U.S.C. § 263b(h)(3)(A), FDA may assess civil money penalties for a "failure to obtain a certificate as required by [42 U.S.C. § 263b(b)]." The MQSA places the duty of obtaining a certificate upon the owner or lessee of a mammography facility, or an authorized agent of either. 42 U.S.C. § 263b(d)(1).

Each Respondent is liable for 193 violations of the MQSA. Respondents failed to obtain a certificate for the period between and including May 7, 2002, and July 25, 2002, during which BIC performed mammography in violation of 42 U.S.C. § 263b(b)(1). Each Respondent is liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A), and for 192 violations pursuant to 42 U.S.C. § 263b(h)(3)(D).

Under 42 U.S.C. § 263b(h)(3)(D), FDA may assess civil money penalties in an amount not to exceed $10,000 for each violation of, or for aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to have a

certificate. Between and including May 7, 2002, and July 25, 2002, Korangy Radiology Associates conducted 192 mammography examinations while the BIC mammography facility was uncertified, in violation of 42 U.S.C. § 263b(b)(1). Accordingly, Respondent BIC is liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D).

Responsible corporate officers are individually liable for violations of public health legislation. See United States v. Dotterweich, 320 U.S. 277, 285 (1943); United States v. Park, 421 U.S. 658, 672-4 (1975); United States v. Hodges X-Ray, Inc., 759 F.2d 557, 560 (6th Cir. 1985). Dr. Korangy was the lead interpreting physician, operator, owner, and employee of BIC at the time of the alleged violations and he had the authority to determine whether Korangy Radiology Associates would continue to perform mammography services. Exhibit G-A; Exhibit G-B; Exhibit G-C; Exhibit G-D. Dr. Korangy, by virtue of his position, had the authority to prevent Korangy Radiology Associates from performing uncertified mammography examinations in violation of 42 U.S.C. § 263b(b)(1). For having failed to prevent these violations, Dr. Korangy is liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate. Dr. Korangy is also liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D), as he was the owner of and most responsible person at, Korangy Radiology Associates at the time of the violations.

Dr. Korangy had notice, by way of the expired mammography certificate itself that Korangy Radiology Associates was performing mammography without a certificate between and including May 7, 2002, and July 25, 2002. Dr. Korangy himself read and interpreted the mammograms from at least 116 of the uncertified examinations. Exhibit G-D ¶ 21; Exhibit G-10. The mammograms from the remaining uncertified examinations were read and interpreted by Irfan S. Shafique, M.D., and Robert J. Hage, D.O. Id. Dr. Korangy, because of his position,

possessed the authority to decide whether Drs. Shafiquc and Hage performed mammography examinations at BIC.

CONCLUSIONS AND ORDER

No genuine issue of material fact exists as to whether Respondents violated the MQSA. Accordingly,

It is ORDERED that Complainant's Motion For Partial Summary Decision of April 2, 2004 is **GRANTED**;

Respondents Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers (BIC), and Dr. Korangy are each liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A). And,

Respondents BIC and Dr. Korangy are each liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D). Thus,

Respondents BIC and Dr. Korangy are each liable for a total of 193 violations of the MQSA. And,

It is Further ORDERED that the remainder of the hearing schedule contained in the order of November 13, 2003 continues in effect, but limited to issues relating to the amount of the penalty to be imposed, including any mitigating circumstances, as set forth in 21 C.F.R. § 17.34.

Dated this 27th day of May, 2004

/s/ Daniel J. Davidson

Daniel J. Davidson
Administrative Law Judge